

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0522V

Filed: 9 August 2010

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ROBERT VERYZER *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

* * * * *

Alan Milstein, Esq., Sherman, Silverstein, Kohl, Rose & Podolsky, Pennsauken, N.J., for Petitioner;
Traci Patton, Esq., United States Department of Justice, Washington, District of Columbia, for
Respondent.

UNPUBLISHED

Decision on the Record Extant; Hepatitis A;
Vascular and Neurological Injuries

UNPUBLISHED DECISION ON THE RECORD¹

ABELL, Special Master:

On 17 July 2006, Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),² alleging that Petitioner, Robert Veryzer, suffered a variety of adverse symptoms, primarily neurological and vascular in nature, and that such was related to the administration of a Hepatitis A vaccine on 25 April 2001. Petition at 1. As an alleged vaccine-related injury, Petitioner demanded compensation. Petition at 9. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation.

¹ Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

² The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I).³ In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine actually caused an injury not so specified. § 11(c)(1)(c).

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. After sincere attempts throughout calendar years 2006 through 2010 to engage a methodologically scientific, thoroughgoing, explanatory medical expert to opine in support of the Petition's claim that the Hepatitis A vaccine actually caused Petitioner's injury, Petitioner moved at a 7 June 2010 status conference for a ruling on the written record, and the Court hereby grants that motion. Respondent filed her Report, pursuant to Rule 4(c), on 16 October 2006, denying compensation, and the Court rules below on the issue of entitlement to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

I. FACTUAL BACKGROUND

On 25 April 2001, Petitioner received both the Hepatitis B and Hepatitis A vaccines. Thereafter, Petitioner suffered ill symptoms of pain and neurological damage, which he believed resulted from the vaccinations he received. On 29 September 2003, Petitioner first filed a petition with this Court, pursuant to 42 U.S.C. § 300aa-11, for compensation of a vaccine-related injury, arising out of his Hepatitis B vaccination (docket no. 03-2252V). At the time of that filing, the Hepatitis A vaccine had not been added to the Vaccine Table, found at 42 C.F.R. § 100.3(a), and a claim for compensation of injury from the Hepatitis A vaccination was not concurrently brought.

That petition faced several uphill challenges of proof, primarily due to trouble finding an expert to opine in support of Petitioner's claim that the Hepatitis B vaccine caused the condition(s) from which Petitioner allegedly suffered. Therefore, on 2 November 2004, Petitioner opted out of the Vaccine Program, "withdrawing" his petition under § 21(b) of the Vaccine Act after receiving the 240-day notice, pursuant to § 12(g) of same.

That case was thus concluded without a final order of the Court, and without the entry of judgment on the petition's claim for compensation. Around that same time, Hepatitis A was added to the Vaccine Table, on 1 December 2004. See 69 Fed. Reg. 69,945-46.

Having finished with the Vaccine Program, Petitioner then sued the vaccine manufacturer, SmithKline Beecham Corp., in the Supreme Court for the State of New York, naming both vaccines as likely culprits for his injuries. However, the vaccine manufacturer objected, arguing that one of

³ The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq.* (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

the two vaccines administered, and upon which Petitioner was litigating (Hepatitis A), was now on the Vaccine Table but that Petitioner had not brought a vaccine claim thereupon. The state court ordered the action dismissed without prejudice by consent, to allow Petitioner to bring another claim to the Vaccine Program, this time for Hepatitis A.

Wherefore, Petitioner filed the instant Petition (docket no. 06-0522V), alleging that Hepatitis A actually caused Petitioner's injuries. In prosecuting the instant Petition, Petitioner initially retained a medical expert witness opining that the injury was necessarily caused by Hepatitis B, but not Hepatitis A or anything else. Petitioner then moved to amend the pending Petition to include a claim for injury allegedly related to his Hepatitis B vaccination, so as to claim recovery for the injury, and to allege causation from the Hepatitis B vaccine. The Court denied the motion to amend (so as to include a claim for injury caused by the Hepatitis B vaccine) based upon 42 U.S.C. § 300aa-11(b)(2) and the doctrine of claim preclusion. Petitioner was then left to found any claim for recovery purely upon the Hepatitis A vaccination, inasmuch as any claim premised upon his Hepatitis B vaccination had been precluded with the prior petition.

After the Court's ruling on that issue, Petitioner sought out an expert whose opinion would support Petitioner's claim that Hepatitis A caused Petitioner's multifarious injuries. Between 26 and 27 August 2008, Petitioner filed expert reports, *curricula vitae*, and supporting documents from Andrew Moulden, M.D., PhD and Sherri Tenpenny, D.O. Respondent filed a motion *in limine* to exclude both of these sets of expert witness materials due to their unreliability of methodology, pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and the Court ultimately granted Respondent's Motion to Exclude.

Following these developments, Petitioner indicated that he would not be filing any other expert materials in support of his Petition, and requested that the Court rule on the record in this case as it now stands.

II. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccine which Petitioner alleges to have caused his condition(s) was the Hepatitis A vaccine, listed under category XIII on the Vaccine Table. Hepatitis A vaccine is associated on the Vaccine Table with no specific injuries or time periods, and thus Petitioner bears the burden of proving actual causation of any injury claimed to be related to that vaccine. 42 C.F.R. § 100.3(a).

In this case, the medical records mention, but do not in any way support, a causative connection between the Hepatitis A vaccination administered and the injuries suffered under an

actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the petitioner's claim of vaccine causation, a medical opinion of sufficient scientific methodology and validity must be offered in support. No medical expert opinion report meeting that standard was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit has articulated in a three-part test its actual causation analysis as follows:

[A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioner has not filed medical records or offered medical expert testimony to proffer, let alone explain, a “medical theory causally connecting the vaccination [to] the injury.” Certainly absent was a detailed analysis of the Record to indicate a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” As such, Petitioner has not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion, *Q.E.F.* There has not been demonstrated to the Court a “a logical sequence of cause and effect showing that the vaccination was the reason for the injury,” *Q.E.D.* See *Althen, supra*.

In short, Petitioner has not met the burden of proof set forth in the Act.⁴ Petitioner has not presented a sufficient amount of evidence required by the Act in the form of corroborative medical records, and failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

III. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

s/ Richard B. Abell
Richard B. Abell
Special Master

⁴ See *Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating “[t]he requirement that [a] petitioner[‘s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone”); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) (“The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.”).